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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,305	03/09/2007	Timothy Hla	UCT0051US2	9420

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CANTOR COLBURN, LLP
20 Church Street
22nd Floor
Hartford, CT 06103

EXAMINER	
FINN, MEGHAN R	

ART UNIT	PAPER NUMBER
1614	

NOTIFICATION DATE	DELIVERY MODE
03/04/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

usptopatentmail@cantorcolburn.com

Office Action Summary	Application No.	Applicant(s)	
	10/562,305	HLA ET AL.	
	Examiner	Art Unit	
	MEGHAN FINN	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *10-21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☒ Claim(s) *4* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 December 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/22/05; 5/10/06; 10/17/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election of Group II the reply filed on October 17, 2008 is acknowledged. Applicant also elected FTY720 as the species of agonist, and adult (acute) respiratory distress syndrome as the disease. The examiner would like to thank the applicant for recognizing that the election required only one disorder and apologizes if there was any confusion. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 10-21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Absent any evidence to the contrary it does not appear that the elected disease (adult (acute) respiratory distress syndrome) reads on claims 10-21 as those are drawn to treatment of unwanted vascular endothelial cell apoptosis, with different and non overlapping diseases claimed in claim 18 or to treatment of a mammal in need of stimulation of new blood vessel formation. Since neither of these appear to be involved in adult (acute) respiratory distress syndrome, and claims 10-21 require different patient populations, they are deemed drawn to the non-elected invention and are withdrawn. Election was made **without** traverse in the reply filed on October 21, 2008.

Applicant has submitted several Information Disclosure Statements (IDS) and the

references were considered except where the reference was crossed out. On the IDS filed May 10, 2006 applicant cites WO 03861567 but does not provide a copy of the reference and thus it was not considered. In the IDS filed October 17, 2007 applicant cited an EPO office action dated 03/09/07, this document was not considered because it has no publication date. Similarly, applicant submitted an IDS filed December 22, 2005 and cited an International Search Report, which has no publication date and was therefore not considered.

Claim Objections

Claim 4 is objected to because of the following informalities: The word "agoniststs" is misspelled on line 6 of claim 4. It appear that applicant means to claim agonists. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 5-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In claim 1, applicant claims a method of treating an individual in need of treatment for a vascular permeability disorder comprising administering a vascular endothelial sphingosine-1-phosphate receptor agonist, wherein that agonist is not sphingosine-1-phosphate. Applicant has disclosed compounds of the formula shown in claim 2, but beyond that applicant has not shown what other compound would be considered endothelial sphingosine-1-phosphate receptor agonists, nor have they indicated that only compounds of that formula are endothelial sphingosine-1-phosphate receptor agonists, nor have they shown a method for determining what compounds would qualify as endothelial sphingosine-1-phosphate receptor agonists as they are not commonly known in the art. Thus one of skill in the art at the time of the invention would not have known what compounds were encompassed by the claims and claim 1 is rejected for lacking written description of the invention. Claims 5-9 are dependent on claim 1, and do not limit the claims to compounds for which there is written description and thus they are also lacking written description of the invention.

Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant has claimed in claim 1, a method of treating vascular permeability disorders, with an endothelial sphingosine-1-phosphate receptor agonist. Applicant has elected FTY720 as the agonist and adult (acute) respiratory distress syndrome as the

disorder. However applicant has not shown their invention such that one of skill in the art at the time of the invention could use the elected species, or any of the compounds encompassed by claim 2 to treat adult (acute) respiratory distress syndrome or other vascular permeability disorders.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in *Ex parte Forman*, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in *In re Wands*, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount of direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

1. The quantity of experimentation necessary to develop a treatment for adult (acute) respiratory distress syndrome with a compound that is not known for treatment of that disease or any related to it is large.

2, 3. Applicant has not provided any direction towards treatment of adult (acute) respiratory distress syndrome. Applicant has demonstrated that FTY720 has some effect on endothelial cell responses in vitro however applicant has not explained how one of skill in the art would translate that to treatment of humans with adult (acute) respiratory distress syndrome. Additionally applicant has provided no direction towards

other compounds of the generic formula in claim 2, either how to make or how to use these compounds.

4, 5. The nature of the invention is treatment of adult (acute) respiratory distress syndrome, and vascular permeability disorders in general. Adult (acute) respiratory distress syndrome is a complicated and unpredictable disease, and the state of the prior art is such that that endothelial sphingosine-1-phosphate receptor agonists are not known to have anything to do with treatment of adult (acute) respiratory distress syndrome.

6. The relative skill of those in the art is high.

7. The unpredictability of treatment of adult (acute) respiratory distress syndrome is also high, and even more so for treatment of other vascular permeability disorders.

8. The breadth of the claims is high due to the large number of compounds encompassed by the generic formula of claim 2, and the large number of diseases encompassed by "a vascular permeability disorder".

Conclusion

No claims are allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Meghan Finn whose telephone number is (571) 270-3281. The examiner can normally be reached on 9:30am-7pm Mon-Thu, 9:30am-6pm Friday (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Meghan Finn

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614